Department of Health & Social Care

Consultation: changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines

A response by the Association of Personal Injury Lawyers

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The benefits of vaccination for public heath are generally acknowledged[1]. Vaccines are an important public health mission and the success of the national vaccination programme is of great importance to the UK and the UK's public health.

The World Health Organisation estimates that vaccines prevented at least 10 million deaths between 2010 and 2015, and many millions more lives were protected from illness[2].

For example, during 2019, about 85 per cent of infants worldwide (116 million infants) received three doses of diphtheria-tetanus-pertussis (DTP3) vaccine, protecting them against infectious diseases that can cause serious illness and disability or be fatal[3].

Despite the success of vaccination programmes across the globe it is accepted that vaccines are not without risks and that regardless of whether there has been negligence or not, adverse events do occur, and that on rare occasion, these adverse events are severe[4].

As a result, all developed countries have adopted statutory vaccine injury compensation schemes in some shape or form. The philosophy underpinning many of these schemes is that a society which requires its citizens to be protected by a vaccination programme should accept the responsibility for the few who suffer injury as a result of it. That, it should be

[1] Looker, C., & Kelly, H. (2011). No-fault compensation following adverse events attributed to vaccination: a review of international programmes. Bull World Health Organ, 371. https://www.who.int/bulletin/volumes/89/5/10-081901/en/

[2] World Health Organisation. (n.d.). The Power of Vaccines: still not fully utilized. https://www.who.int/publications/10-year-review/vaccines/en/

[3] World Health Organisation. (n.d.). The Power of Vaccines: still not fully utilized. *Ibid*.

[4] Collet, J., MacDonald, N., Cashman, N., Pless, R., & The Advisory Committee on Causality Assessment. (2000). Monitoring signals for vaccine safety: the assessment of individual adverse event reports by an expert advisory committee. Bulletin of the World Health Organization. https://apps.who.int/iris/handle/10665/268060

acknowledged, there is a moral case for compensation[5]. (Pearson, Royal Commission, 1978).

At all times, but more so during a pandemic such as is being experienced now, we believe that the UK Government should promote vaccination by providing an assurance to consumers that in the rare event of an adverse reaction to a vaccine resulting in significant injury, the consumer will be able to obtain full compensation for the injuries suffered.

Unfortunately the scheme set up by the existing Vaccine Damage Payments Act 1979 was not fit for purpose even before the outbreak of the Covid-19 pandemic. The debate surrounding the Bill was described by Lord Allen of Abbeydale as follows: "the Bill was discussed by one and all on the basis that it was a temporary measure which would hold the field until conclusions had been reached on the recommendations of the Royal Commission"[6]. The temporary became the permanent and has remained largely unchanged ever since. The Act's faults include:

- The Act requires the consumer to prove that he/she has suffered 'severe disablement' to an extent of 60 per cent or more.
- At that severe level of disablement, the scheme pays a one-off derisory £120,000 compensatory lump sum (which is the equivalent of 24 percent of the £500,000 capped limit for damages payable under the Criminal Injuries Compensation Scheme).
- Cases are scientifically and/or medically complex but there is no provision for legal costs or any other support for those who wish to make a claim under the scheme. It excludes some routinely administered vaccines such as that for hepatitis, for example, even though the hepatitis B vaccine is routinely available as part of the NHS vaccination schedule and is offered to those thought to be at increased risk of hepatitis B or its complications. DOH guidance states that "all healthcare workers who may have direct contact with patients' blood, blood-stained body fluids or tissues, require vaccination [with Hepatitis B vaccine]. This includes any staff at risk of injury from blood-contaminated sharp instruments, or of being deliberately injured or bitten by patients."[7]. Rare side effects of the Hepatitis vaccine include: angioedema; apnoea; arthritis; encephalitis; encephalopathy; hypotension; meningitis; multiple sclerosis;

[5] Pearson, Royal Commission. (1978). Royal Commission on Civil Liability and Compensation for Personal Injury. para. 1397, 296.
[6] UK Parliament. (1984, March 7). Vaccine Damage Payments Act 1979: Anomalies. Hansard, 449.
[7] Public Health England. (2013, March). Immunisation of Healthcare and Laboratory Staff. Green Book, Chapter 12. https://www.gov.uk/government/publications/immunisation-of-healthcare-and-laboratory-staff-the-green-book-chapter-12

muscle weakness; nerve disorders; paralysis; seizure; thrombocytopenia; vasculitis[8] Many of these conditions can lead to severe disablement.

- As currently drafted, the Vaccine Damage Payments Act does not include injury arising from any Covid-related vaccines or (in respect of adults) flu vaccines.

The payments under the scheme since its inception have been paltry. Between 1978 and October 2019 there have been only 942 successful claims (resulting in total payments of £74,790,000) out of a total 6,368 claims received by the scheme (14.8% of claims received have been successful).[9] In contrast, under the United States National Vaccine Compensation Scheme a total of 7542 awards were made between 1988 and 2020 resulting in payments to victims totalling $4,059,338,346. Lawyers who represented claimants also received remuneration.[10]

Alongside the Vaccine Damage Payments Act 1979, British consumers can also bring a product liability claim under the Consumer Protection Act (CPA).

It is notable that there has never been a successful claim against a vaccine manufacturer in this country. In fact, there has also never been a successful claim against anyone in relation to administration of a vaccine. It is fair to say that the UK has a very difficult, ungenerous system and there is a view among lawyers that vaccine cases are hopeless and cannot be won. Claimant consumers face costs of around £5m to £10 million to bring a case to trial. Because of the poor prospects of success, it is very unlikely to find anyone who would be willing to embark on bringing such a claim to trial. Legal aid funding is virtually impossible to obtain for such claims.

Licensing issues

It is useful to compare what is being proposed in this pandemic with what happened during the swine flu pandemic of 2009/10.

In the swine flu pandemic, the European Medicines Agency (EMA) licensed vaccines before

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[8] UK BNF (British National Formulary) content published by NICE https://bnf.nice.org.uk/drug/hepatitis-b-vaccine.html

[9] Department of Work and Pensions - Freedom of Information Act response Ref: FOI2019/37020, 18th October 2019 https://www.whatdotheyknow.com/request/610185/response/1452951/attach/2/37020%20WDTK%20Template%20reply.pdf?cookie_passthrough=1

[10] HRSA (Health Resources & Services Administration) National Vaccine Injury Compensation Program Monthly Statistics Report, updated 1 September 2020: https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/data/data-statistics-report.pdf

full clinical trials had been completed[11 & 12] on the basis that these types of vaccine were considered to have a long track record of safety and it was considered that the risk of licensing a vaccine which was not fully tested was justified by the benefits to be obtained by preventing potential mass loss of life.

To create a new vaccine takes up to around ten years to fully develop and test, but in a pandemic there is no time to do that. In 2009 the EMA licensed the swine flu vaccines even though they had not completed the necessary clinical trials in relation to children and adults. It is accepted there were around 2,000 cases of narcolepsy which resulted from the vaccine: one in 50,000 doses of the vaccine was linked with the adverse event of narcolepsy. It would have required a clinical trial of 50,000 individuals to have detected one case of narcolepsy. In the case of the proposed Covid-19 vaccines manufacturers are conducting clinical trials of the vaccine on a tiny number of individuals and so the level of clinical testing is very low. (See '*Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial'* the Lancet, 20 July 2020 and '*Everything you need to know about the Oxford coronavirus vaccine' by* Michael le Page in New Scientist, 21 July 2020, both of which suggest the clinical trial involves 1,000 individuals).

Put within this context, the proposals contained in this consultation paper are surprising and unusual. In the opening paragraphs, the consultation indicates that "Any vaccine must first go through the usual rigorous testing and development process and be shown to meet the expected high standards of safety, quality and efficacy before it can be deployed."

We agree, which begs the question that if a vaccine has gone through all its development processes, has passed its standard clinical testing and gone through the usual trials, then it should be able to demonstrate that it is a safe medicine and should be capable of being licensed.

So if it is correct that, on the face of this consultation, the vaccine has gone past all the usual rigorous tests and trials, then it should be licensed and the issue of claims in respect of the use of unlicensed vaccines should not arise.

We strongly support the statement that it should go through the usual testing and development processes. As we have seen in relation to, for example, the Pandemrix

[11] Cook, S. (2009, 09 29). European agency approves swine flu vaccines for licensing. British Medical Journal, 339 https://www.bmj.com/content/339/bmj.b3992
[12] European Medicines Agency. (2009, 10 2). *European Medicines Agency recommends authorisation of additional vaccine for influenza pandemic (H1N1) 2009*: https://bit.ly/2FwtLY3

vaccine for swine flu, even before all of its clinical trials were concluded, it was still licensed by the EMA on the basis of preliminary information and the Government underwrote the manufacturer's liability risk.

We are concerned that it has clearly not been possible to demonstrate the minimum requisite level of safety required for licensing even on the basis of preliminary information; otherwise it would have been licensed.

In such circumstances there is a valid question as to whether it is appropriate to use an unlicensed product. It would only be ethical if consumers were given a very clear explanation of the potential risks and were able to give informed consent to those risks at the point when they were vaccinated. Consumers should be told they will be vaccinated with an unlicensed product which has not yet demonstrated the standards of safety which would usually be expected. They should also be told that the manufacturers are supplying it only on the basis that they are being indemnified against any claims (if that is the case).

There are concerns about how practical this would be to do: therefore if an overall decision is being made to recommend a particular vaccine, then (as was recommended in the Pearson Commission) the government should underwrite and accept liability in the event significant injury is caused.

Informed consent: *Montgomery*

The decision in *Montgomery v Lanarkshire Health Board*[13] defined the standard for informed consent and disclosure. Previously, the *Bolam test*[14] in England & Wales and the *Hunter v Hanley test*[15] in Scotland determined what should be disclosed by a doctor to a patient when considering the treatment being offered. Both tests permitted a doctor to decide what was in the patient's best interests to disclose before obtaining the patient's consent: their conduct would be judged by that which was supported by a responsible body of clinicians. *Montgomery* firmly rejected this approach to consent, establishing a duty of care to warn of material risks: whether "a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it." A more 'patient focused' test.

Unfortunately, this consultation removes the need for an informed *Montgomery* standard of consent by ensuring that no claims will be possible against the manufacturer, and the

[13] [2015] SC11
[14] *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582
[15] *Hunter v Hanley* [1955] SC 200, 1955 SLT 213

unlikely event of any claims being brought under the CPA for the reasons outlined above.

The consultation also proposes immunity for the healthcare worker or vaccinator alongside the manufacturer who supplies the unauthorised vaccine. While it is true that theoretically a claim could be brought under the CPA, no claim as ever succeeded. There are many defences and difficulties and liability is in state of ferment after recent decisions: there is very little practical risk of a product liability claim.

The risk of the being vaccinated with an unlicensed vaccine needs to be weighed up by the individual who should be provided with good and accurate information. If this consultation's proposals are in place, then there will be no need to give good and accurate information and the public will be dragooned into being vaccinated, with no realistic recourse for compensation in the event of a severe adverse reaction. It is unethical that a vaccine could be administered in such circumstances where legislation actively encourages a wilful lack of information or warning given to the consumer.

This is particularly pertinent now. There has never been a successful coronavirus vaccine. The likely candidate vaccine may employ a completely novel mechanism. The proposed Oxford vaccine, we understand, involves priming the immune system with a chimpanzee cold virus to deliver the gene for the coronavirus spike protein to human cells: a mechanism which has not been used in a UK vaccine[16].

With a new mechanism in a vaccine, the risk is higher: it is only when the vaccine is given to a large population that rare adverse events will be identified. It may be that in the clinical trials all look fine, but when given to millions of people, our immune systems are not all the same: they will react differently and auto immune illnesses are a real risk[17]. A high-risk situation – potentially new mechanism in a vaccine so the risk to consumers must be high.

This is especially so with Covid-19 as its effect on the human body is still poorly understood.

Given that it is proposed to disapply the prohibition on promoting an unlicensed medicine to healthcare professionals and the public as part of a national campaign, it is vitally important that before being vaccinated, individuals are given good, impartial advice and information. Regrettably this proposed framework will discourage that.

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[16] Pedro M Folegatti, M. e. (2020, July 20). *Safety and immunogenicity of the ChAdOx1 nCoV-19 vaccine against SARS-CoV-2: a preliminary report of a phase 1/2, single-blind, randomised controlled trial.* The Lancet. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31604-4/fulltext

[17] See Philip Krause et al, (2020, September 12). *COVID-19 vaccine trials should seek worthwhile efficacy.* The Lancet. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31821-3/fulltext#.X2CS0CAUDCo.twitter

Extension of immunity to other non-covid-19 vaccination claims

It is opportunistic of the government to use this pandemic as a Trojan horse to extend its proposed immunity from suit to claims arising from other vaccines and other related claims.

There are other entirely valid injury claims which may arise as a result of the administration of the vaccine, rather than due to any defect with the vaccine. For example, if a vaccination is incorrectly administered, it can result in a type of shoulder injury usually referred to as Shoulder Injury Related to Vaccine Administration, or SIRVA. SIRVA is a rare condition in which pain and loss of function in the shoulder occurs following a vaccination. It can result in shoulder pain, weakness, stiffness or nerve inflammation. In very rare cases, it can result in nerve injury. Currently, injured consumers would have a claim in negligence against the healthcare professional who administered the vaccine.

This consultation seeks to close down the consumer's right to pursue any claim (not only those relating to adverse effects due to the vaccine itself against) the vaccinator. An individual who, according to these proposals, may be a member of the 'expanded workforce' authorised to administer the vaccine, having not done so either before or sufficiently regularly before this pandemic and who may, as a result cause such injuries.

In short, this consultation document proposes no safeguards or redress for members of the public who receive the vaccine; indeed it seeks to remove or reduce existing rights, while giving substantially increased protection from lawsuits to manufacturers and others involved in the administration of vaccines.

Final comments

It is regrettable that the Government seeks to use the Covid-19 pandemic as a vehicle to remove, wholesale, rights of redress from individual consumers who, by answering its call to take part in a national immunisation campaign, suffer an adverse event and are permanently injured as a result.

A society which requires its citizens to be protected by a vaccination programme should accept the responsibility for the few who suffer injury as a result of all vaccinations licensed in this country.

The Government has an opportunity to improve the lot for the tiny number of consumers who are injured, improving the safety net to ensure that for the good of the majority, they will not be forgotten or ignored.

Fortunately, severe adverse reactions resulting in significant injury are exceedingly rare: the overall cost of a compensation scheme would be very low. The cost of a scheme would be offset by the costs saved by the increased rate of immunisation resulting from consumer confidence that they would be protected in the extremely rare circumstance that they suffered a significant adverse reaction to immunisation.

Failure to implement such a safety net creates a significant risk of damage to public confidence in vaccines which could be potentially damaging to public health.

About APIL

The Association of Personal Injury Lawyers (APIL) is a not-for-profit organisation which has worked for 30 years to help injured people gain the access to justice they need, and to which they are entitled. We have more than 3,000 members who are committed to supporting the association's aims, and all are signed up to APIL's code of conduct and consumer charter. Membership comprises mostly solicitors, along with barristers, legal executives, paralegals and some academics.

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